

## **REMARKS**

### **Introduction**

Claims 4-8, 12, and 20 are pending. Claims 4-8, 12, and 20 have been amended. Support for these amendments can be found throughout the specification, for example, in the claims as filed and the working examples.

Claims 1-3, 9-11, 13-19, and 21-28 have been cancelled without prejudice to the subject matter described therein. Applicant expressly reserves the right to pursue the subject matter of the cancelled claims in this application or in another application.

### **Rejection under 35 U.S.C. §101**

Claims 4-8, 12 and 19-23 have been rejected under 35 U.S.C. §101 as allegedly lacking utility. Specifically, the Examiner has rejected the claims as allegedly lacking utility because there was an insufficient correlation between the expression of DAX-1 and its function in neurodegenerative diseases in humans. Applicant traverses.

To expedite prosecution, Applicant has amended the claims so that the non-human animal claimed is a mouse or a fly. The claimed disease has also been limited to Alzheimer's disease. Applicant respectfully asserts that the claimed methods have at least uses as models for studying Alzheimer's disease and as models for studying modulation of the DAX-1 gene *in vivo*. Other uses are also apparent and these are provided as non-limiting examples.

In view of the amended claims, Applicant believes the rejection under 35 U.S.C. §101 has been overcome and/or rendered moot. Withdrawal of this rejection is respectfully requested.

## **Rejections under 35 U.S.C. §112**

### A. 112 First Paragraph

#### *1. Enablement*

The Examiner has rejected claims 4-8, 12, and 19-23 under 35 U.S.C. §112 as allegedly lacking enablement. Applicant traverses.

To expedite prosecution, the claims have been amended to narrow their scope. The amended claims are directed to mice or flies having a non-native gene sequence coding for DAX-1 as opposed to any non-human transgenic animal with such a gene sequence. The claims are also now directed to only Alzheimer's disease not neurodegenerative diseases in general. These amended claims are well supported in the specification as filed, for example, by the working examples.

Therefore, one of skill in the art would be able to make and use the claimed invention when considering the specification in combination with the state of the art at the time of filing. Applicant respectfully asserts that this rejection has been overcome. Withdrawal of the rejection is requested.

#### *2. Written Description*

The Examiner has rejected claims 4-8, 12, and 19-23 under 35 U.S.C. §112 as allegedly lacking written description. Applicant traverses.

To expedite prosecution, the claims have been amended to remove the "fragment, derivative, or variant thereof" language that was the basis for this rejection. This rejection is now moot. Withdrawal of this rejection is respectfully requested.

B. 112 Second Paragraph

The Examiner has rejected claims 6-7 and 8 under 35 U.S.C. § 112 second paragraph as allegedly being indefinite. Applicant traverses.

To expedite prosecution, the claims have been amended. Claim 6 has been amended to clarify that the animal displays symptoms of Alzheimer's disease or a predisposition for Alzheimer's disease. Claims 6 and 7 have been amended to remove the and/or language the Examiner has called out in the Office Action. Finally, claim 8 has been amended to clarify that the non-human animals are used as an experimental model for at least one step of the method of developing therapeutics or diagnostics.

In view of these amendments, Applicant believes these rejections are now moot and/or have been overcome. Withdrawal of these rejections is respectfully requested.

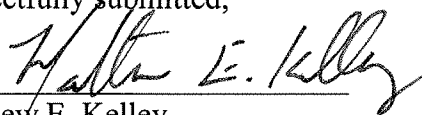
**CONCLUSION**

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. Applicant believes that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is hereby invited to telephone the undersigned at the number provided.

The Commissioner is authorized to charge any deficiency in any patent application processing fees pursuant to 37 CFR § 1.17, including extension of time fees pursuant to 37 CFR § 1.17(a)-(d), associated with this communication and to credit any excess payment to Deposit Account No. 22-0261.

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Respectfully submitted,

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